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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/764,359	01/19/2001	Lola M. Reid	320727.50601	7133

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EXAMINER

NGUYEN, QUANG

ART UNIT	PAPER NUMBER
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1633

DATE MAILED: 01/12/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/764,359

Applicant(s)

REID ET AL.

Examiner

Quang Nguyen, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 October 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3,4,6-9,12-21 and 23-34 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,3,4,6-9,12-21 and 23-34 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Applicant's amendment filed on 10/17/05 has been entered.

Claims 1, 3-4, 6-9, 12-21 and 23-34 are pending in the present application, and they are examined on the merits herein.

Response to Amendment

The New Matter rejection is withdrawn in light of Applicant's amendment.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 23-34 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. ***This is a modified rejection.***

In amended claim 23 and its dependent claims, there is still no nexus between the recited steps (a)-(b) and the preamble reciting "processing a liver tissue". This is because both the harvesting and processing steps do not even require a liver tissue as claimed. Clarification is requested because the metes and bounds of the claims are not clearly determined.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1, 3-4, 6-9, 12-21 and 23-34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Reid et al. (WO 95/13697; IDS) in view of Faris (U.S. 6,129,911 with the effective filing date of 7/10/1998; Cited previously) and Brockbank et al. (WO 91/07086). ***This is a new ground of rejection.***

Reid et al. disclose methods for isolating hepatoblasts comprising liver stem cells (pluripotent precursors) and committed precursors for either hepatocytes and bile duct cells using panning technologies and multiparametric FAC sorting from a single cell suspension of liver cells (see Summary of Invention). Reid et al. state "The methods of the invention have been developed using embryonic and neonatal livers from rats, however, the method of the invention offers a systemic approach to isolating

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hepatoblasts from any age from any species" (page 4, lines 6-10). This statement includes the isolation of hepatoblasts from adult liver (see page 43). Reid et al. also note that hepatoblasts that are found in a high proportion of liver cells in early embryonic livers and in small number located periportally in adult livers (page 3, line 35 continues to line 1 of page 4). In the disclosed method (page 14, lines 9-15 for example), livers were dissected from donors, and placed into fresh ice-cold HBSS (should be about 4⁰C). Reid et al. also teach that the tendency of isolated cells to aggregate is prevented by maintaining the cells at 4⁰C and by removing calcium with EGTA (page 39, lines 24-33). Panned cells in the methods taught by Reid et al are sorted for multiple markers that distinguish subcategories of hepatic precursor cell populations, with the identified markers include: (a) the extent of granularity as measured by side scatter on fluorescence activated cell sorting, (b) the extent of autofluorescence and (c) the expression of a hepatic cell marker (page 12, lines 23-34).

Reid et al do not specifically teach a method of processing a non-fetal donor liver tissue or procuring liver progenitor cells from a liver tissue obtained between about 2 hours and about 30 hours postmortem.

At the effective filing date of the present application (1/19/00), Faris also taught methods for isolating liver cell clusters comprising a liver stem cell and a hepatocyte, and a population of isolated liver stem cells from adult liver tissues from various species such as a mouse, a pig or a human; and that the liver tissues can be obtained from mammalian organ donors including deceased donors or cadavers (these donors do not have heart-beats, see col. 5, lines 3-25 and Summary of Invention). Brockbank et al

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also taught that ischemia ensues rapidly upon death of an organism, and that the susceptibility of a particular tissue to ischemia must be considered, particularly for transplantation, with kidneys being the most susceptible tissues to ischemia and that they must be procured immediately after cessation of donor heartbeat while bone marrow can tolerate at least 12 hours of warm ischemia postmortem (page 1, lines 11-27).

Accordingly, it would have been obvious for an ordinary skilled artisan in the art to modify the teachings of Reid et al. by also obtaining liver tissues from deceased donors or cadavers, including human deceased donors and cadavers, for the preparation of hepatoblast cell populations and that these liver tissues should be obtained as fresh as possible to avoid cell death in the harvested tissues caused by warm ischemia that ensues rapidly upon death of an organism in light of the teachings of Faris and Brockbank et al. Additionally, any time frame between about 2 hours and about 30 hours postmortem would also be obvious considering the time that it would require to process the deceased donors or cadavers before the liver tissues can be harvested, and there is also a higher availability of liver tissues that are no longer suitable for transplantation due to the about 2 hours of warm ischemia.

An ordinary skilled artisan would have been motivated to carry out the above modification because liver tissues from deceased donors and cadavers, particularly from humans, in any time frame between about 2 hours and about 30 hours postmortem are available for obtaining an enriched population of liver stem and/or progenitor cells.

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An ordinary skilled artisan would have a reasonable expectation of success to carry out the above modification in light of the teachings of Reid et al, Farris, and Brockbank et al., coupled with a high level of skills of an ordinary skilled artisan in the relevant art.

Therefore, the claimed invention as a whole was *prima facie* obvious in the absence of evidence to the contrary.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Quang Nguyen, Ph.D., whose telephone number is (571) 272-0776.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's primary, Celine Qian, Ph.D., may be reached at (571) 272-0777, or SPE, Dave Nguyen, at (571) 272-0731.

To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit 1633; Central Fax No. (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It

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also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.



QUANG NGUYEN, PH.D
PATENT EXAMINER